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APPLICANTS: Min et al.
SERIAL NO.: 09/937,875
FILED: October 1, 2001
TITLE: "A RATE ADAPTIVE PACEMAKER"

Assistant Commissioner for Patents
Washington, D.C. 20231

S I R:

Applicants herewith submit a certified copy of Swedish Application No. 9901194-2, filed in the Swedish Patent Office on March 31, 1999, on which Applicants base their claim for convention priority under 35 U.S.C. § 119.

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This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

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(21)	*Patentansökningsnummer* *Patent application number*	*9901194-2*
(86)	*Ingivningsdatum* *Date of filing*	*1999-03-31*

Stockholm, 1999-10-12

För Patent- och registreringsverket
For the Patent- and Registration Office

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Technical Field

The present invention relates to a rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low.

Background Art

The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is previously known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus US-A-4,535,774 describes a stroke volume controlled pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in US-A-5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night time setting of a lower rate limit to a lower value than the pacemaker daytime setting of the lower rate limit.

Thus, too low a pacing rate may cause too slow influx of blood enriched with oxygen. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough not to disturb a peaceful sleep. In that case the patient can

feel more healthy in various everyday life conditions including peaceful sleeping.

The purpose of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented in a new way from becoming too low, such that the above discussed inconveniences for the patient are avoided.

<u>Disclosure of the Invention</u>

This purpose is obtained by a rate adaptive pacemaker according to claim 1.

Thus, by satisfying two predetermined relations the pacemaker according to the invention ensures a sufficient minimum energy supply to the patient's organism or body and at the same time the maximum value of the stroke volume is limited and these conditions are continuously automatically checked.

Preferred embodiments are set forth in the dependent claims.

According to an advantageous embodiment of the pacemaker according to the invention the first predetermined relation is

$$CO > CO_{rest} \qquad (1)$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L \qquad (2)$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5. In this way the actual cardiac output is ensured not to become lower than the rest state cardiac output CO_{rest} and the actual stroke volume is ensured to be less than a maximum allowed value equal to $L \times SV_{rest}$, where L typically has a value between 1.2 and 1.5, depending on the health of the patient's myocardium. By satisfying both these conditions simultaneously a physio-

logically well founded heart work management at low work loads is ensured.

According to other advantageous embodiments of the pacemaker according to the invention the pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output (CO_{rest}) for the patent in rest conditions, and the relation between actual stroke volume (SV) and a maximum allowed stroke volume (SV_{max}) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means, and said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke volume SV with stroke volume SV_{rest} for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L \qquad (3)$$

is satisfied and said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV) \qquad (4)$$

where HR_{rest} denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate HR_{rest} for rest conditions of the patient.

According to still another advantageous embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac

output CO and actual stroke volume SV from the measured cardiac bioimpedance. In this way these parameters are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac electrode and the housing of the pacemaker, when an excitation current proceeds from the electrode tip.

Brief Description of the Drawings

The invention will now be described more in detail with reference to the enclosed drawings on which figure 1 is a block diagram of an embodiment chosen as an example of the pacemaker according to the invention and figure 2 illustrates the principle of bioimpedance measurements between the tip of an intracardial electrode and the metal housing of the pacemaker.

Description of a Preferred Embodiment

To avoid that the current cardiac output CO

$$CO = SV \times HR \qquad (5)$$

becomes lower than the rest state cardiac output CO_{rest} the pacing rate must be above a lower pacing rate limit given by

$$\text{lower pacing rate limit} = (CO_{rest})/(SV) \qquad (6)$$

and since

$$CO_{rest} = HR_{rest} \times SV_{rest} \qquad (7)$$

$$\text{lower pacing rate limit} = (HR_{rest}) \times (SV_{rest}/SV) \qquad (8)$$

In addition thereto the maximum value of the stroke volume must be limited, i.e.

$$SV_{max} < L \times SV_{rest} \qquad (9)$$

Thus, the following two conditions must be fulfilled simultaneously for insuring a physiologically well founded heart work management at low work loads.

$$\text{Pacing rate limit} > (HR_{rest}) \times (SV_{rest}/SV) \qquad (10)$$

$$SV/SV_{rest} < L \qquad (11)$$

where L is a constant typically equal to a value of 1.2 to 1.5, depending on the health of the patient's myocardium.

Thus the lower pacing rate limit is continuously automatically calculated from the measured actual stroke volume SV and known values of SV_{rest}, HR_{rest} and the constant L. The actual stroke volume can be determined from e.g. bioimpedance measurements as will be described below.

Figure 1 is a block diagram of an embodiment of the pacemaker according to the invention comprising a bioimpedance measurement unit 2 for measuring the time variation of the electric intracardiac bioimpedance $Z_c(t)$. This type of measurements is well known, see e.g. "Design of Cardiac Pacemakers", edited by John G. Webster, IEEE Press, 1995, pp. 380-386 and US-A-5,154,171, 5,280,429, 5,282,840 and 5,807,272. Thus the time variation of the intracardiac bioimpedance can be measured between the tip 4 of the intracardiac electrode 6 and the housing 8 of the pacemaker, when an excitation current is fed from the electrode tip 4, as schematically illustrated in figure 2. Thus a standard pacing lead can be used for this measurement.

From the measured time variations $\Delta Z_c(t)$ the stroke volume SV needed for calculating the lower pacing rate limit according to equation (8) above, or for checking the inequalities (10) or (11), are determined in computing means 10, see figure 1.

The calculated lower limit value is supplied to a lower limit setting means 12 of a pacing rate limiter 14.

A pacing rate controller 16 is also provided for controlling the pacing rate of the pacer or pulse generator 18 in response to the patient's demands. In a limiting unit 20 of the limiter 14 the demanded pacing rate is compared to the set lower limit pacing rate and the actual pacing rate is limited to the set lower limit value if the demanded pacing rate reaches this limit value. Thus in the pacemaker according to the invention a lower limit value for the pacing rate is continuously automatically determined and it is continuously automatically verified that the actual pacing rate does not exceed the present lower limit value.

Alternatively, the pacemaker can be modified to continuously monitor that the inequalities (10) or (11) above are satisfied.

Above bioimpedance measurements are described for determining the stroke volume SV. This parameter can, however, also be determined by other techniques, like by ECG measurements, by ultrasound technique, etc.

Claims

1. A rate adaptive pacemaker comprising a means for determining the demand of the patient´s organism, a pacing rate controlling means for controlling the pacing rate in response to the patient´s demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low, **characterized in** that said pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output (CO_{rest}) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and maximum allowed stroke volume (SV_{max}).

2. The pacemaker according to claim 1, **characterized in** that said first predetermined relation is

$$CO > CO_{rest}$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L$$

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5.

3. The pacemaker according to claims 1 or 2, **characterized in** that said pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output (CO_{rest}) for the patient in rest conditions and the relation between actual stroke volume (SV) and a maximum allowed stroke volume (SV_{max}) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means.

4. The pacemaker according to claim 3, **characterized in** that said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke

volume SV with stroke volume SV_{rest} for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L$$

is satisfied, and in that said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV)$$

where HR_{rest} denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied.

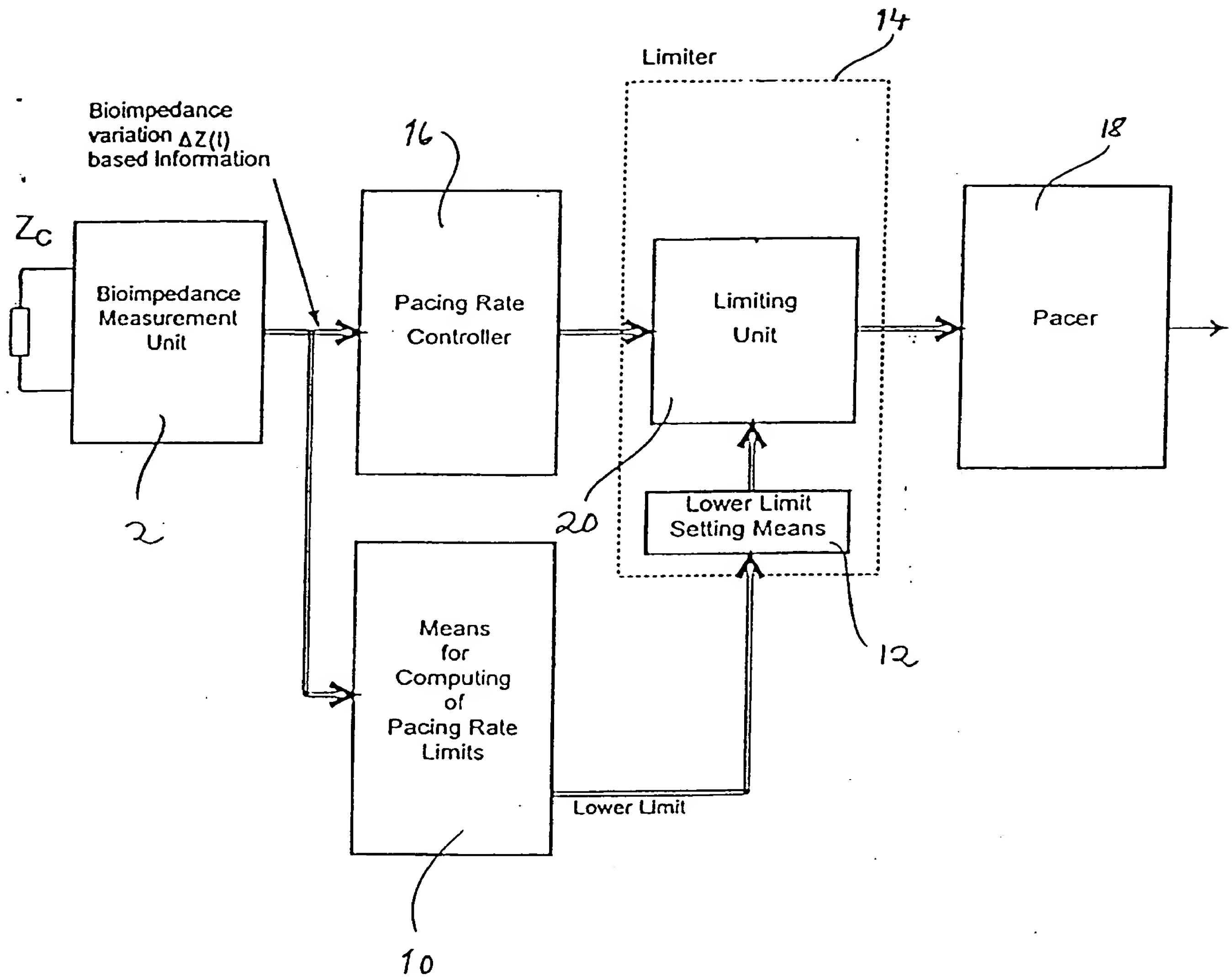
5. The pacemaker according to any of the claims 2 - 4, **characterized in** that a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output (CO) and actual stroke volume (SV) from the measured cardiac bioimpedance.

6. The pacemaker according to any of the claims 2 - 4, **characterized in** that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

Abstract

A rate adaptive pacemaker comprises a means (2) for determining the demand of the patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (20) for preventing the pacing rate from becoming too low. The pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output (CO_{rest}) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and maximum allowed stroke volume (SV_{max}).

Figure 1


14
Limiter
Bioimpedance
variation ΔZ(t)
based Information
16
18
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Bioimpedance
Measurement
Unit
Pacing Rate
Controller
Limiting
Unit
Pacer
2
20
Lower Limit
Setting Means
Means
for
Computing
of
Pacing Rate
Limits
12
Lower Limit
10

Fig. 1

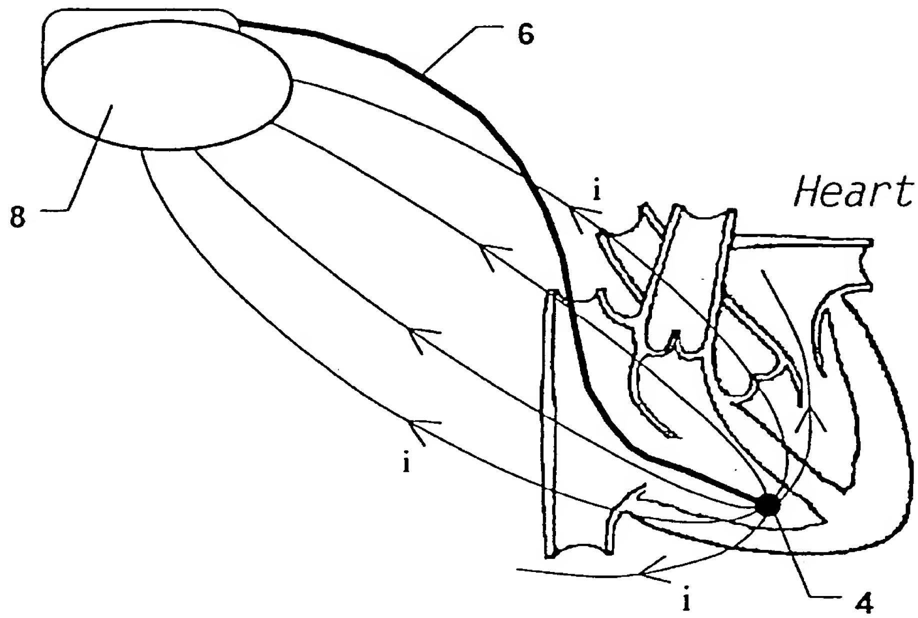

Fig. 2